Atty. Dkt. No. 029099-0106

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

U.S. Patent No. 5,888,510

Issued: March 30, 1999

Inventors: Tadamitsu KISHIMOTO et al.

Applicants: Chugai Seiyaku Kabushiki Kaisha
Tadamitsu Kishimoto

Product: Actemra® (tocilizumab), humanized anti-human IL-6R monoclonal antibody

TRANSMITTAL

Mail Stop Hatch Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Please find enclosed the following documents filed in connection with the above referenced patent:

1. Hoffman-La Roche regulatory activity authorization letter in support of Application for Extension of Patent Term Under 35 USC §156.

2. Submission under 37 CFR §1.765 to support previously filed Application for Extension of Patent Term Under 35 USC § 156.

Respectfully submitted,

Date March 8, 2010

By _____

FOLEY & LARDNER LLP
Foley & Lardner LLP
3000 K Street, N.W.
Washington, D.C. 20007-5143
Tel: 202-672-5300
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Stephen B. Maebius
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

U.S. Patent No. 5,888,510

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Product: Actemra® (tocilizumab), humanized anti-human IL-6R monoclonal antibody

SUBMISSION UNDER 37 CFR § 1.765 TO SUPPORT PREVIOUSLY FILED APPLICATION FOR PATENT TERM EXTENSION UNDER 35 U.S.C. §156

Mail Stop: Hatch Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir or Madam:

Applicant hereby advises the U.S. Patent and Trademark Office that applications for extension of the term of U.S. Patent Nos. 5,795,965 and 5,670,373 have been filed which are also based on the regulatory approval of a Biologics License Application (BLA # 125276/0) on January 8, 2010, for Actemra® (tocilizumab)

Respectfully submitted,

Date March 8, 2010

By _____

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Stephen B. Maebius
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George W. Johnston
Vice President and Chief Patent Counsel
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Roche

March 8, 2010

Mr. Manabu Takahama
Chugai Pharmaceutical Co., Ltd.
Intellectual Property Department
200 Kajiwara, Kamakura
Kanagawa, 247-8530 JAPAN

Re: Actemra® Infusion Approval - USA

Dear Mr. Takahama,

By this letter, Hoffmann-La Roche Inc. ("Roche"), the holder of the BLA for Actemra®, confirms its prior and continuing authorization for Chugai Pharmaceutical Co., Ltd. ("Chugai") to rely upon Roche's regulatory activities with respect to Actemra® before the United States Food and Drug Administration ("FDA") as a basis for the recently filed applications to extend the terms of US Patent Nos. 5,795,965; 5,670,373; and 5,888,510. Roche's BLA 125276/0 was submitted on November 19, 2007 and references IND No. 11972 filed on October 5, 2004. As you know, the FDA approved Actemra® for marketing by Roche in the USA on January 8, 2010.

Please feel free to submit this correspondence to the United States Patent and Trademark Office as a confirmation of our authorization to Chugai.

Very truly yours,

George W. Johnston

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